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EXAMINER	
GRAY, R	

ART UNIT	PAPER NUMBER
3301/1026	5

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DATE MAILED: 10/26/93

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 7/22/93 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ___ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☒ Notice re Patent Drawing, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1-13 are pending in the application.
   Of the above, claims 6-8 and 10 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-5, 9, and 11-13 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 9-89)

Claims 6-8 and 10 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected species. Election was made **without** traverse in Paper No. 4.

The drawings are objected to because Figure 1 must be labelled as prior art. Correction is required.

Claims 1-5, 9, and 11-13 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 "the bone-like structure" lacks antecedent basis, and it is unclear what would fall within the scope of the term "bone-like".

In claim 2 "the bone-like tissue" lacks antecedent basis, and it is unclear what would fall within the scope of the term "bone-like".

It is unclear how claim 3 further limits claim 1 from which it depends, if at all, since it only claims structure which does not manipulatively affect any of the method steps claimed.

In claim 4 "the scanning step" and "the data base" lack antecedent basis.

In claim 5 "the data base" and "the hard tissue" lack antecedent basis.

In claim 9 it is unclear whether the words "which are cemented together" is claiming a step of cementing, or whether

this claim is merely describing the structure and does not affect the only claimed method step of fabricating.

Claims 3 and 9 are rejected under 35 U.S.C. § 112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim. These claims appear to only describe structure which does not manipulatively affect any of the claimed method steps.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-3, 12, and 13 are rejected under 35 U.S.C. § 102(a) as being clearly anticipated by Bresina et al. (The Treatment of Bone Defects).

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 4 and 5 are rejected under 35 U.S.C. § 103 as being unpatentable over Bresina et al.in view of Walker et al..

Bresina et al. disclose all steps claimed except for the scanning including scanning a healthy animal's body part and archiving the data for subsequent use, and modifying the data base to make selected changes in the size and shape of the hard tissue represented by the data base. Walker et al. teach using archived data gathered by imaging a healthy animal's body part to design an implantable prosthesis and to make selected changes in the size and shape of the archived data in order to suit the particular needs of the patient at hand. In view of the teaching of Walder et al., it would have been obvious to one of ordinary skill in the art to modify Bresina et al.'s method of making an implantable prosthesis so that the scanning step includes scanning a healthy animal's body part (since a normal counterpart which can be mirrored does not always exist on the patient at hand), and modifying the gathered data of the healthy animal's body part to suit the particular patient at hand.

Claims 9 and 11 are rejected under 35 U.S.C. § 103 as being unpatentable over Bresina et al. in view of Cima et al. (THREE DIMENSIONAL PRINTING: FORM, MATERIALS, AND PERFORMANCE). Bresina et al. disclose that it is known in the prosthesis art to custom create a prosthesis by sequentially solidifying adjoining intervals of a fluid material along an axis. As taught by Cima et al., it is known to sequentially adjoin intervals of a fluid

material along an axis using the steps claimed. Therefore, it would have been obvious to one of ordinary skill in the art to make a prosthesis using the steps claimed to sequentially adjoing intervals of a fluid material along an axis.

Any inquiry concerning this communication should be directed to Randy Shay at telephone number (703) 308-2907.

Randy C. Shay
Primary Examiner
Art Unit 338

R. Shay

October 12, 1993